### In the Specification

Please amend the specification as follows:

At page 1, line 14, after "filed July 10, 1996," delete "for which a notice of allowance was mailed on May 12, 1998 for which an issue fee was paid on May 19, 1998." and replace with --now Patent No. 5,815,591.--

At page 2, line 21, delete "improves" and replace with --improve--.

## I. Introduction

In the Office Action of January 4, 2000, the Examiner rejected claims 1, 10 and 15 under 35 U.S.C. § 103(a). The Examiner objected to claims 2-9, 11-14, and 16-20, but indicated that such claims would be allowable if rewritten in independent form including all limitations of the base claim and any intervening claims. Applicants appreciate indication of allowable subject matter. The Examiner suggested a change to Applicants' reference to an earlier filed application which applicants have incorporated. The Examiner further suggested a change to the specification which Applicants have also incorporated.

By means of the present office action response, the specification has been amended as suggested by the Examiner. No claims have been added, deleted or amended. Applicants respectfully urge the Examiner to reconsider the above rejections in light of the following remarks, and respectfully submit that pending claims 1-20 are in condition for allowance.

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# A. Rejected Claims Under 35 U.S.C. § 103(a)

The Examiner rejected claims 1, 10 and 15 under 35 U.S.C. § 103(a) as being unpatentable over Giger et. al. (USP 5,657,362), in view of Merickel et al. (USP 5,003,979) and further in view of Gur et al. (USP 5,627,907). Applicants respectfully traverse such rejection on the basis that Giger and Merickel do not teach or suggest combining these reference, and on the basis that Merickel does not teach the claim limitation (independent spiculation detection) as asserted by the Examiner.

To provide context for Applicants' comments, a summary of a preferred embodiment of the invention is useful. Applicants teach an algorithm for detecting suspicious portions of digital mammograms by using independently calculated mass and spiculation information. In the algorithm, an x-ray mammogram is scanned and digitized into a digital mammogram. In a preferred embodiment, spiculation detection and mass detection are then carried out independently, in that there is no data dependence between them. In particular, the spiculation detection step does not require any final or intermediate outputs from the mass detection step, and the mass detection step does not require any final or intermediate outputs from the spiculation detection step. In addition to introducing the ability to make the overall algorithm faster, the independence of the mass detection and spiculation detection steps allows for increased detection of features characteristic of architectural distortions, radial scars, and, in general, otherwise suspicious lesions that do not have a significant central mass that is detected by the mass detection algorithm.

With mass and spiculation information, a classifier algorithm is performed on feature vectors corresponding to locations in the digital mammogram. Each location in the digital

mammogram has a corresponding feature vector, which can be defined as a set of characteristics, including the "massness" metrics and "spiculatedness" metrics. A classifier is an algorithm or system that labels a feature vector as belonging to a specific class, such as "suspicious/normal," "malignant/benign," etc. Finally, the digital mammogram image and a list of suspicious lesions are sent to a viewing station for display to a radiologist or doctor.

The independent nature of mass detection and spiculation detection is important because it solves the problem of prior art in which a mass detection algorithm and a spiculation detection algorithm are serially and dependently applied. In the prior art, a mass detection algorithm is applied to the digitized image first so that areas with "density," or mass, can be identified. In this way, a mass detection algorithm making a "first cut" singles out only areas that may contain suspicious masses. Next, a spiculation detection algorithm is applied only to those suspicious areas that may contain masses, rather than to the entire mammographic image. Thus, spiculated masses with low density may be overlooked. In contrast, by applying both a spiculation detection algorithm and a mass detection algorithm to the entire image, Applicants' invention is likely to identify an increased number of suspicious areas. For example, areas containing low density spiculated masses may be identified.

## 1. Merickel Does Not Teach Independent Spiculation Detection

At page 5 of the Office Action, the Examiner stated, "Giger is silent about specific details regarding the means for computing mass and spiculation information independently."

Applicants agree. However, the Examiner goes on to state, "Merickel deals with only spiculation

information ..." Id. Applicants respectfully disagree with the Examiner's characterization of Merickel.

Merickel teaches producing multiple sequences of image slices by noninvasive scanning using, for example, MRI or PET. Merickel at Col. 3:37-57. Merickel then teaches classifying different image types by applying, to the image slices, classifier parameters from a training set. Id. at Col. 5:56-6:10. The boundary shape (i.e., the size and shape of the lesion noted by the Examiner at pg. 5 of the Office Action) of the tissue types of interest is then determined. Merickel at Col. 8:30-9:24. Merickel states, "The classifiers exhibit successful recognition of regions corresponding to normal breast fat, breast carcinoma, and fibrous or mixed tissues." Id. at 9:8-11. Thus, the breast carcinoma and fibrous or mixed tissues are masses or lesions which are identified using the algorithm described. Having identified a lesion, Merickel further describes a refinement to the lesion detection algorithm which characterizes the shape of the lesion. Id. at Col. 9:26-28. Benign lesions are ignored ("Since only suspect lesions are of interest, the benign regions are usually not refined." Id. at Col. 10:30-31). Using polar coordinates and Fourier techniques, Merickel teaches a method for determining whether an identified lesion is spiculated or lobulated which could indicate malignancy. Id. at Col. 9:37-45.

To summarize, Merickel teaches identifying lesions including breast carcinoma and fibrous or mixed tissue. Using this information, Merickel then determines whether the identified lesion is spiculated or lobulated. Thus, Merickel does not perform a spiculation algorithm independent of a mass detection algorithm as recited in Applicants' claims. Rather, Merickel essentially practices the prior art wherein a mass detection algorithm makes a "first cut" to single out only areas that may contain suspicious masses, and then a spiculation detection algorithm is

applied only to those suspicious areas that may contain masses, rather than to the entire mammographic image. See, Applicants' Specification at pg. 3, line 9 - pg. 4, line 22.

Thus, with reference to Applicants' claim 15, Merickel does not disclose "computing spiculation information corresponding to the digitized mammogram independent of said mass information." The Examiner admits and Applicants agree that Giger does not disclose such element; moreover, Gur does not teach any kind of spiculation detection. Thus, claim 15 is not made obvious by Giger et. al. (USP 5,657,362), in view of Merickel et al. (USP 5,003,979) and further in view of Gur et al. (USP 5,627,907).

Furthermore, for analogous reasons, claims 1 and 10 are not anticipated nor made obvious by Giger et. al. (USP 5,657,362), in view of Merickel et al. (USP 5,003,979) and further in view of Gur et al. (USP 5,627,907). Therefore, Applicants respectfully request reconsideration and withdrawal of the § 103(a) rejection of Applicants' claims 1, 10 and 15.

Because claims 2-9, 11-14 and 16-20 depend upon allowable claims 1, 10 and 15, respectively, claims 2-9, 11-14 and 16-20 are also allowable. Therefore, Applicants respectfully request reconsideration and withdrawal of the Examiner's rejections and objections of claims 2 2-9, 11-14 and 16-20.

# 2. No Basis Exists For Combining or Modifying Giger with Merickel

The Examiner asserts that the teachings of Giger can be modified with the teachings of Merickel to achieve independent spiculation detection. Office Action at pg. 5. As noted above, the combination of Giger or Merickel does not suggest independent spiculation detection.

Moreover, there is nothing in the prior art that suggests in some way a modification of Giger with Merickel.

Giger is generally directed to the detection of lesions in x-ray mammograms (Giger at Col. 4:22-28), whereas Merickel is generally directed to the detection of lesions in cross-sectional MRI or PET images of the breast (Merickel at Col. 1:52-2:2). As such, while Giger and Merickel are both concerned with the detection of breast cancer, they start with different types of data.

Despite the Examiners assertion that Giger and Merickel are in the same field of endeavor, the technologies are different and cannot readily be combined. Absent a showing in the prior art of a teaching, suggestion or incentive to combine the Giger reference using x-ray imaging with the Merickel reference using cross-sectional MRI or PET imaging, the Examiner has impermissibly used "hindsight' occasioned by Applicants' teaching to search through the prior art for the claimed elements to combine them. The Federal Circuit has expressly prohibited this:

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, *absent some teaching, suggestion or incentive* supporting the combination. ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984).

In re Geiger, 815 F.2d 686, 688, 2 U.S.P.Q.2d 1276, 1278 (Fed. Cir. 1987) (emphasis added).

Indeed, such an approach is "an illogical and inappropriate process by which to determine patentability." Sensonics, Inc. v. Aerosonic Corp., 81 F.3d 1566, 1570, 36 U.S.P.Q.2d 1551, 1554 (Fed. Cir. 1996). Thus, the Examiner's § 103(a) rejections are improper and should be withdrawn for this reason also.

### **SUMMARY**

Claims 1-20 are pending in the present application. In view of above arguments, allowance is respectfully requested of all pending claims as the pending claims meet all of the requirements for patentability and are in condition for allowance.

Early notification to this effect and expedited prosecution to issuance is earnestly solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call Frank Morris, a representative of the Applicants, at (212) 790-9090.

The commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 16-1150 for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

Dated: July 5, 2000

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Enclosure